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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,247	07/13/2000	Michael Zasloff	036870-5062-01	5537

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,247	ZASLOFF ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *May 24, 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment and response filed on May 24, 2005 wherein claims 1-13 are cancelled and claims 14-30 are newly submitted.

Currently, claims 14-30 are pending in this application and under examination on the merits.

This application is a continuation in part of 08/857288 now patented 6,143,738 which claims priority from Provisional Applications 60017627 and 60029541.

However, the parent case 08/857288 now patented 6,143,738 which claims priority from Provisional Applications 60017627 and 60029541 upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the new claims 14-30 of this application as to methods for reducing blood cholesterol levels in a mammal, since the parent case merely discloses a method for treating diabetes and/or obesity in a mammal.

Therefore, the filing date of the instant claims as to methods for reducing blood cholesterol levels in a mammal, is deemed to be the filing date of the instant application, July 14, 2000.

If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

In clarifying the priority date of the instant claims, applicant should note or address whether the art rejections are prior to the priority date of the instant claims and whether said art occurred more than one year prior to said priority date. Applicant will note that the art rejections are under both 35 U.S.C. § 102(a) and 102(b) because the priority date of the instant claims is in question.

Applicant's amendment regarding the cancellation of claim 1 filed on May 24, 2005 with respect to the rejection of claim 1 made under the judicially created doctrine of obviousness-type double patenting over claims 1-16 of U.S. Patent No. 6,143,738 of record stated in the Office Action February 24, 2005 have been considered and are found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Moreover, the new claims 14-30 are not seen to be obviousness-type double patenting over claims 1-16 of U.S. Patent No. 6,143,738.

Applicant's amendment filed on May 24, 2005 with respect to the rejection of claims 1, 4-6 and 12-13 made under 35 U.S.C. 112 second paragraph for indefinite recitation, of record stated in the Office Action dated February 24, 2005 have been fully considered and found persuasive to remove the rejection since these claims have been cancelled. Therefore, the said rejection is withdrawn.

The following is new rejection(s) necessitated by Applicant's amendment filed on May 24, 2005, wherein all original claims are cancelled. Therefore, all prior art rejections of record in the previous Office Action February 24, 2005 are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zasloff et al. (5,792,635) or Zasloff et al. (5,842,740) in view of the Merck Manual of Diagnosis and Therapy (17^{th} ED).

Zasloff et al. (5,792,635) discloses that administering the instant compound, compound 1436 (see its structure at col.9-10, 115-116, 159) with a pharmaceutically acceptable carrier (see col.4 line 61-65), is useful in methods of treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and anti-ateriosclerotic, and diabetic composition and diabetes, and hypertension in a mammal (see col. 4 line 5-15; col.1 line 63-65; col.2 line 21-22). Zasloff et al. also discloses that the dose to be effective in treating diabetes, or effect on insulin secretion is 20 mg/kg/day or by 10 mg/kg, i.v., twice a day (see col.83, Table 11), which is within the instant claimed range.

Zasloff et al. (5,842,740) discloses that administering the instant compound, compound 412 (see its structure at col.41-42) and compound 1436 (see col. 9-10) with a pharmaceutically acceptable carrier (see col.4 line 61-65), is useful in methods of treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and anti-ateriosclerotic, and diabetic composition and diabetes, and hypertension in a mammal (see col. 4 line 5-15; col.1 line 63-65; col.2 line 21-22). Zasloff et al. also discloses that the dose to be effective in treating diabetes, or effect on insulin secretion is 20 mg/kg/day or by 10 mg/kg, i.v., twice a day (see col.79, Table 11), which is within the instant claimed range.

Zasloff et al. do not expressly disclose the employment of the compound therein in a method of reducing blood cholesterol levels in a mammal or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes.

Note that Zasloff's method treats atherosclerosis in a mammal since atherosclerosis is a known generic term for diseases including cardiac infarction, angina pectoris and ischemic disorders of the heart, and ateriosclerotic diseases, and diabetic composition and diabetes, hypercholesteremia and hypertension in a mammal (see the Merck Manual of Diagnosis and Therapy,17th ED, page 1654-1656). The Merck Manual of Diagnosis and Therapy also teaches that elevated serum cholesterol or hypercholesterol, hypertension diabetes mellitus, and obesity are the major risk factors for atherosclerosis (see page 1656 both left and right column entitled by "Risk Factors" and subtitles "Hypertension", "Diabetes mellitus" and "obesity").

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular compound of Zasloff et al., in methods of treating serum cholesterol, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular compound of Zasloff et al., in methods of treating hypercholesteremia, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes, since the prior art compounds are known to be used in treating cardiac infarction, angina pectoris and ischemic disorders of the heart, and ateriosclerotic diseases, and diabetic composition and diabetes, and hypertension in a mammal. Moreover, elevated serum cholesterol or hypercholesteremia, hypertension, diabetes mellitus, and obesity are well known major risk factors for atherosclerosis and associated with atherosclerosis according to The Merck Manual of Diagnosis and Therapy.

Therefore, one of ordinary skill in the art would have reasonably expected that the prior art compounds, would have beneficial therapeutic effects and usefulness in methods of treating hypercholesteremia, or elevated serum cholesterol, or reducing blood cholesterol levels in a mammal suffering hypercholesteremia or a mammal suffering hypercholesteremia associated with diabetes.

Moreover, the patient population for atherosclerosis or diabetes or cardiac infarction, angina pectoris and ischemic disorders of the heart, is reasonably interpreted to encompass or overlap or coincide those patients suffering elevated serum cholesterol as claimed herein, in particular those hypercholesteremia associated with atherosclerosis or diabetes.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed May 24, 2005 with respect to the rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. These remarks are believed to be adequately addressed by the new ground obvious rejection presented above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
July 27, 2005